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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/608,584 | 06/26/2003 | Sho-Ya Wang | 0794.047 | 8433 |
| 23405 | 7590 | 10/18/2005 | EXAMINER | |
| HESLIN ROTHENBERG FARLEY & MESITI PC 5 COLUMBIA CIRCLE ALBANY, NY 12203 | | | CHANDRA, GYAN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1646 | |

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/608,584 | WANG, SHO-YA | |
| | Examiner Gyan Chandra | Art Unit 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 August 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 and 31-45 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-14 and 31-45 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 08 August 2005 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

Claims 15-30 are canceled.

Claims 1-14, and 31-45 are pending and under examination.

Response to Arguments

Applicant's arguments, see Remarks, filed 8/8/2005, with respect to objection to the drawing have been fully considered and are persuasive. The objection of drawing has been withdrawn.

The objection to the specification because of the following informalities: Page 1, paragraph 0003, line 13, the word "peudotetrameric structure" is read as "pseudotetrameric structure" has been withdrawn in view amendment to the specification.

Claim Rejections - 35 USC § 112 first paragraph-written description

The rejection of claims 1-14 and 31-45 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the reasons of records in the previous Office Action.

Claims are drawn to a method of assessing the potential of a compound to function as an anti-arrhythmic agent comprising a cell expressing a recombinant mutant Nav 1 sodium channel protein. The invention is further drawn to Nav 1 mutants having one or more amino acid among the ten amino acids occurring at the carboxy end of the S6 segments of D1, D2, D3 or D4 domains of mammalian Nav1 protein that differs from the amino acid in wild type Nav 1 by substitutions of tryptophan, phenylalanine, tyrosine,

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or cysteine. The claims do not require that the polypeptides possess any particular conserved structure, or any other disclosed distinguished feature. Thus the claims are drawn to a genus of amino acids that is defined by a large number of amino acid substitutions.

Applicant argues that invention has the same amino acid sequence as the corresponding wild type mammalian Nav1, except that the last 10 amino acids of S6 segments of D1, D2, D3 and D4 domains that can be substituted with one of tryptophan, phenylalanine, tyrosine, or cysteine amino acids. Applicant further argues that these mutations/substations possibilities would be less than innumerable possibilities. Further, Applicant provides a paper copy sequence and accession number Q9WTU3 for the Nav 1.6 in mouse pointing towards sequence homology.

Applicants' arguments have been fully considered but they are not found to be persuasive because claims are drawn to Nav 1 mutants having one or more amino acid among the ten amino acids occurring at the carboxy end of the S6 segments of D1, D2, D3 or D4 domains of mammalian Nav1 protein that differs from the amino acid in wild type Nav 1 by substitutions of tryptophan, phenylalanine, tyrosine, or cysteine. Thus in total there are 40 different positions where one or more possible substitutions can be made in different possible combinations. These are still a huge number of substations to make and test for a functional aspect of Nav1. The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making a mutation.

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Further, since previously submitted sequence does not have a computer readable file (CRF) of the polypeptide sequence for Q9WTU3 as per Sequence compliance rule, a precise sequence comparison of Q9WTU3 sequence with Nav1 sequence cannot be made.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra, Ph.D.
Art Unit 1646
30 September 2005



JANET L. ANDRES
SUPERVISORY PATENT EXAMINER